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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,143	07/30/2003	Kenneth W. Hunter	IMMUSONIC-005-1	9478

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,143	HUNTER ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the response of 30NOV2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-4, 11, and 12 are pending.

2. Claims 1-4, 11, and 12 are elected and rejected.

3. Claims 1-6 and 18-21 are non-elected and withdrawn from consideration and cancelled by applicant in the amendment of November 30, 2005.

Election/Restrictions

1. Applicant's election of Group I, corresponding to claims 1-4 and 11-12 in the reply filed on November 30, 2005 is acknowledged. In addition, the election of November 30, 2005 cancelled the non-elected claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

2. *Regents of the University of California v. Eli Lilly & Co..*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S.Ct. 1548 (1980), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure...." Enzo Biochem, Inc. v. Gen-Probe., 296 F.3d, 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp.2d 216, 225 (W.D.N.Y 2003).

5. The claims are directed to methods of expressing an increased number of B7 molecules on the surface of an antigen presenting cell (APC) to enhance or regulate an immune system comprising the steps of: administering a glucan-containing composition to an animal or a human; in order to cause increased expression of co-stimulatory molecules and, allowing an up regulation of B7 molecules on a APC molecules. These

claims fail to meet the written description requirement for the following reasons. The phrase *co-stimulatory molecules* is written functionally. There is insufficient descriptive support for the functional phrase *co-stimulatory molecules* in the instant specification. In addition, the instant specification does not describe what is meant by the functional characteristics of being known as *co-stimulatory molecules*. Structural identifying characteristics of the phrase *co-stimulatory molecules* are not disclosed. There is no evidence that there is any per se structure/function relationship between the disclosed phrase of *co-stimulatory molecules* and any others that might be found using the claimed method. Furthermore, there is no support that the particularly disclosed phrase of an *co-stimulatory molecules* is represented by the sole examples of B7 molecules of B7.1, B7.2, and B7.3. The specification does; however, provide an adequate written description of the *co-stimulatory molecules* of B7 molecules of B7.1, B7.2, and B7.3. There is no description of an actual reduction to practice, each step of the claimed method to show that the applicant was in possession of the claimed invention. Therefore, the claim fails to comply with the written description requirement. In the absence of some understanding of the term of the functional phrase of *co-stimulatory molecules* other than adequately described of B7 molecules of B7.1, B7.2, and B7.3, the artisan would not have accepted that the applicant was in possession of the claimed method as currently written.

6. Claims 1, 3, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. There is insufficient descriptive support for the phrase *a glucan-containing composition*. In addition, the instant specification does not describe what is meant by the phrase *a glucan-containing composition* other than β-1,3-glucans and β-1,6-glucans. Structural identifying characteristics of the phrase *a glucan-containing composition* are not disclosed except for those β-1,3-glucans and β-1,6-glucans. There is no evidence that there is any per se structure/function relationship between the phrase, *a glucan-containing composition* other than those disclosed, namely β-1,3-glucans and β-1,6-glucans. The instant specification does not provide an adequate written description for the phrase *a glucan-containing composition*. Accordingly, these claims fail to comply with the written description requirement.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rationale supports this rejection. Claim 4 is rejected as being an improper Markush claim. It is improper to use the term "comprising" instead of "consisting of." *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931) and MPEP 2173.05(h). Although the instant claim uses the transitional phrase

"including" it is synonymous with the transitional phrase of "comprising", which is considered open-ended and does not exclude additional, unrecited elements or method steps, see MPEP 2111.03. Accordingly, the lack of clarity rejection may be corrected by replacing the word "including" for the phrase –consisting of -- into claim 4.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 has improper claim dependency on cancelled claim 5. It appears that claim 4 should depend on claim 3 instead of claim 5.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Rorstad et al. of U.S. Patent No. 5,401,727. Rorstad et al. are directed to a process for stimulating the immune system and/or enhancing the resistance by administering immunostimulatory compounds, such as glucans. In fact, Rorstad et al. teach that the specific glucans that have β-1,3- glycosidic bonds and β-1,6 glycosidic bonds are

immunostimulatory compounds that act are used to enhance the resistance of a subject in need thereof, (see columns 1 and 2). Rorstad et al. teach that these immunostimulatory compounds of glucans that have β-1,3- glycosidic bonds and β-1,6 glycosidic bonds can be administered in a variety of routes such as enterally or parenterally as well as listing various pharmaceutically acceptable carriers for these pharmaceutical preparations with the immunostimulatory compounds of glucans that have β-1,3- glycosidic bonds and β-1,6 glycosidic bonds, (see columns 7 and 8).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Adachi, Y. et al. Adachi, Y. et al. teach of utilizing β-1,3-D-glucans on the generation of cytotoxic T lymphocytes in order to increase cellular immunity. In addition, Adachi, Y. et al. teach that β-1,3-D-glucans mediated the production of B7 molecules, namely B7-1 and B7-2 molecules, which in turn induced antigenic cytotoxic T lymphocytes as well as the expression of cell-surface molecules, (see Abstract).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rorstad et al. of U.S. Patent No. 5,401,727 in view of Ostrand-Rosenberg et al. of U.S. Patent No. 5,858,776. Rorstad et al. are directed to a process for stimulating the immune system and/or enhancing the resistance by administering immunostimulatory compounds, such as glucans. In fact, Rorstad et al. teach that the specific glucans that have beta-1,3 glycosidic bonds and beta-1,6 glycosidic bonds are immunostimulatory compounds that act are used to enhance the resistance of a subject in need thereof, (see columns 1 and 2). Rorstad et al. teach that these immunostimulatory compounds of glucans that have beta-1,3 glycosidic bonds and beta-1,6 glycosidic bonds can be administered in a variety of routes such as enterally or parenterally as well as listing various pharmaceutically acceptable carriers for these pharmaceutical preparations with the immunostimulatory compounds of glucans that have beta-1,3- glycosidic bonds and beta-1,6 glycosidic bonds, (see columns 7 and 8).

12. The prior art reference of Ostrand-Rosenberg et al. teach that T cell activation requires an antigen-specific signal, often called a primary activation signal, which results from stimulation of a T cell receptor present on the surface of the T cell. Ostrand-Rosenberg et al. also disclose that this antigen-specific signal is usually in the form of

an antigenic peptide bound either to a major hisotcompatibility complex (MHC) class I protein or an MHC class II protein present on the surface of an antigen present cell (APC). Ostrand-Rosenberg et al. further teach that these class II molecules are found on a limited number of cell types, such as B cells, monocytes/macrophages, and dendritic cells. In addition to an antigen-specific primary activation signal, T cells also require a second, non-antigen specific, signal to induce full T cell proliferation and/or cytokine production, which are known as costimulation. The costimulatory molecule is triggered by a molecule on the surface of the APC, just like the antigen-specific signal. Ostrand-Rosenberg et al. further teach that the B lymphocyte antigen B7 is a costimulatory molecule. In addition, Ostrand-Rosenberg et al. further teach that B-lymphocytes, in particular B7, are costimulatory molecules that activate antigen-presenting cells. Accordingly, it would have been obvious one having ordinary skill in the art to select any other member of the B lymphocyte family, especially when the prior art reference of Ostrand-Rosenberg et al. disclose that B lymphocytes, in particular B7, are costimulatory molecules that activate antigen presenting cells, (see column 1). In fact, Rorstad et al. do teach of a variety of carriers and modes of administration, (see columns 7 and 8). The determination of a dosage and mode of administration, such as for injection administrations, like im for vaccines, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing unwanted and/or adverse side-effects. Hence, the combination of references makes the instant invention obvious to one having ordinary skill in the art.

13. Claims 1-4, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adachi, Y. et al. Adachi, Y. et al. teach of utilizing β-1,3-D-glucans on the generation of cytotoxic T lymphocytes in order to increase cellular immunity. In addition, Adachi, Y. et al. teach that β-1,3-D-glucans mediated the production of B7 molecules, namely B7-1 and B7-2 molecules, which in turn induced antigenic cytotoxic T lymphocytes as well as the expression of cell-surface molecules, (see Abstract). Adachi, Y. et al. is silent to a vaccine. However, the determination of a dosage and mode of administration, such as for injection administrations, like im for vaccines, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing unwanted and/or adverse side-effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-

direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

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DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
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